

DEP § REF  
Room 307

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



Application of: Ezio BOMBARDELLI *et al.*

Confirmation No.: 7670

Application No.: 10/608,213

Art Unit: 1651

Filed: June 30, 2003

Examiner: To Be Assigned

For: METHODS OF TREATMENT USING A SOYA EXTRACT Attorney Docket No.: 7914-100-999

**REQUEST FOR REFUND UNDER 37 CFR § 1.28(a)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

A filing fee in excess of the required fee has been paid in connection with the subject application. In particular, a filing fee of \$918.00 has been paid when, in fact, a fee of \$750.00 should have been paid.

The subject application was filed in the U.S. Patent and Trademark Office on June 30, 2003.

Applicant recently received the enclosed copy of the " Filing Receipt" for this application on September 29, 2003. It was only during a review of the filing receipt that this error was discovered. The filing receipt indicates that there are a total of nineteen (19) claims of which five (5) are independent. As shown on the enclosed filing transmittal sheet and preliminary amendment, there are ten (10) claims of which three (3) are independent. A copy of the Filing Receipt with the date received stamped thereon is also enclosed herewith.

Please refund the excess filing fee in the amount of \$168.00 to Pennie & Edmonds LLP Deposit Account No. 16-1150. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

Date October 9, 2003

Paul E. Dietze

For: Thomas G. Rowan

Reg. No. 45,627

Reg. No. 34,419

**PENNIE & EDMONDS LLP**

1667 K Street, N.W.

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Enclosures



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/608,213	06/30/2003	1651	918	7914-100-999	1	19	5

20582  
 PENNIE & EDMONDS LLP  
 1667 K STREET NW  
 SUITE 1000  
 WASHINGTON, DC 20006



CONFIRMATION NO. 7670

## FILING RECEIPT



\*OC000000010934418\*

Date Mailed: 09/26/2003

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

## Applicant(s)

Ezio Bombardelli, Milano, ITALY;  
 Bruno Gabetta, Milano, ITALY;

P.E.D

SEP 29 2003

## Assignment For Published Patent Application

Indena SpA;

## Domestic Priority data as claimed by applicant

This application is a DIV of 09/902,226 07/11/2001 PAT 6,607,757  
 which is a DIV of 09/492,921 01/28/2000 PAT 6,280,777  
 which is a CIP of PCT/EP98/04770 07/30/1998

## Foreign Applications

GERMANY 197 32 866.0 07/30/1997  
 GERMANY 197 32 855.5 07/30/1997  
 GERMANY 197 32 822.9 07/30/1997

If Required, Foreign Filing License Granted: 09/26/2003

Projected Publication Date: 01/08/2004

Non-Publication Request: No

Early Publication Request: No

**Title**

Methods or treatment using a soya extract

**Preliminary Class**

424

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**LICENSE FOR FOREIGN FILING UNDER  
Title 35, United States Code, Section 184  
Title 37, Code of Federal Regulations, 5.11 & 5.15**

**GRANTED**

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

**NOT GRANTED**

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Prior application: Examiner M. FloodArt Unit 1654

Commissioner for Patents  
P.O. Box 1450  
Mail Stop PATENT APPLICATION  
Alexandria, VA 22313-1450

Sir:

This is a request for filing a ☐ continuation ☒ divisional application under 37 CFR § 1.53(b), of pending prior application no. 09/902,226 filed on July 11, 2001.

of Ezio BOMBARDELLI and Bruto GABETTA

(inventor(s) currently of record in prior application)

for SOYA EXTRACT, PROCESS FOR ITS PREPARATION AND PHARMACEUTICAL COMPOSITION

(title of invention)

1. ☒ The filing fee is calculated below:

## PATENT APPLICATION FEE VALUE

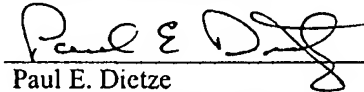
TYPE	NO. FILED	LESS	EXTRA	EXTRA RATE	FEE
Total Claims	10	- 20	0	\$18.00 each	\$ 0.00
Independent	3	- 3	0	\$84.00 each	\$ 0.00
Minimum Fee					\$ 750.00
Multiple Dependency Fee If Applicable (\$280.00)					\$ 0.00
<b>Total</b>					\$ 750.00
Applicant qualifies for the 50% Reduction for Independent Inventor, Nonprofit Organization or Small Business Concern					\$ 0.00
<b>Total Filing Fee</b>					\$ 750.00

2. ☒ Please enter the Preliminary Amendment submitted herewith before calculating the fees due.
3. ☒ Please charge the required fee to Pennie & Edmonds LLP Deposit Account No. 16-1150. A copy of this sheet is enclosed.
- 4a. ☐ New formal drawings are enclosed.
- 4b. ☐ Informal drawings are enclosed.
- 5a. ☒ Priority of application no. 197 32 866.0, filed on July 30, 1997 in Germany; application no. 197 32 855.5, filed on July 30, 1997 in Germany; application no. 197 32 822.9, filed on July 30, 1997 in Germany is claimed under 35 U.S.C. §119.
- 5b. ☒ The certified copy has been filed in prior application no. 09/492,921, filed January 28, 2000.

6. ☒ The prior application is assigned of record to Indena SpA by virtue of an assignment executed on February 29, 2000 and recorded on April 11, 2000 at Reel 010753/Frame 0223 in prior application no. 09/492,921, filed January 28, 2000.
- 7a. ☒ The Power of Attorney appears in the original papers in prior application no. 09/492,921, filed January 28, 2000.
- 7b. ☐ A Power of Attorney is enclosed.
8. ☐ This application contains nucleic acid and/or amino acid sequences required to be disclosed in a Sequence Listing under 37 CFR §§1.821-1.825. It is requested that the Sequence Listing in computer readable form from prior application no., filed on be made a part of the present application as provided for by 37 C.F.R. §1.821(e). The sequences disclosed therein are the same as the sequences disclosed in this application. A copy of the paper Sequence Listing from application no. is enclosed.
9. ☐ The undersigned states, under 37 C.F.R. §1.821(f), that the content of the enclosed paper Sequence Listing from application no. is the same as the content of the computer readable form submitted in application no. .
10. ☐ DO NOT PUBLISH. I hereby certify that the invention disclosed in the attached application has not and will not be the subject of an application filed in another country, or under a multilateral agreement, that requires publication at eighteen months after filing. I hereby request that the attached application not be published under 35 U.S.C. 122(b).
11. ☒ Additional enclosures or instruction: Preliminary Amendment and Information Disclosure Statement

Respectfully submitted,

Date June 30, 2003



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Ezio Bombardelli *et al.*

Serial No.:	To be assigned (Divisional of 09/902,226, filed July 11, 2001)	Art Unit:	To be assigned
Filed:	Concurrently Herewith	Examiner:	To be assigned
For:	METHODS OF TREATMENT USING A SOYA EXTRACT (as amended)	Attorney Docket No:	7914-100-999

**PRELIMINARY AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Prior to examination of the accompanying application, please enter the following amendments and remarks into the file of the above-captioned application.

**Amendments to the Title** begin on page 2 of this paper.

**Amendments to the Specification** begin on page 3 of this paper.

**Amendments to the Claims** are reflected in the listing of the claims that begins on page 4 of this paper.

**Remarks** begin on page 7 of this paper.

**Amendments to the Title:**

Please amend the title as follows:

METHODS OF TREATMENT USING A SOYA EXTRACT;  
~~PROCESS FOR ITS PREPARATION AND PHARMACEUTICAL COMPOSITION~~

**Amendments to the Specification:**

On page 1, following the title, please insert the following:

**CROSS REFERENCE TO RELATED APPLICATIONS**

This is a divisional of U.S. Patent Application Serial No. 09/902,226, filed July 11, 2001, now allowed, which is a divisional of U.S. Patent Application Serial No. 09/492,921, filed January 28, 2000, now U.S. Patent No. 6,280,777, each of which is incorporated herein by reference in its entirety.

This listing of claims will replace all prior versions and listings of claims in the application:

**Listing of the Claims:**

5. (Amended): A method of treating pre- or post-menopausal symptoms in a female subject ~~which comprises~~ comprising administering to a female subject ~~in need of such treatment~~ a therapeutically effective amount of the a soya extract of claim 1 comprising:

(a) glucoside isoflavones in an amount of at least 13 % by weight; and

(b) 0.6 to 1.5 parts by weight of group B soya saponins per 1 part by weight of the glucoside isoflavones.

6. (Amended): ~~A method of treating pre or post menopausal symptoms in a female subject which comprises administering to a female subject in need of such treatment a therapeutically effective amount of the soya extract of claim 2~~ The method of claim 5, wherein the soya extract comprises 1 part by weight of group B soya saponins per 1 part by weight of the glucoside isoflavones.

7. (Amended): A method of treating cancer in a subject ~~which comprises~~ comprising administering to a subject ~~in need of such treatment~~ a therapeutically effective amount of the a soya extract of claim 1 comprising:

(a) glucoside isoflavones in an amount of at least 13 % by weight; and

(b) 0.6 to 1.5 parts by weight of group B soya saponins per 1 part by weight of the glucoside isoflavones.

8. (Amended): ~~A method of treating cancer in a subject which comprises administering to a subject in need of such treatment a therapeutically effective amount of the soya extract of claim 2~~ The method of claim 7, wherein the soya extract

comprises 1 part by weight of group B soya saponins per 1 part by weight of the glucoside isoflavones.

9. (Original): The method of claim 7 wherein the subject is a female and the cancer is breast cancer.

10. (Original): The method of claim 8 wherein the subject is a female and the cancer is breast cancer.

11. (Original): The method of claim 7 wherein the subject is a male and the cancer is prostate cancer.

12. (Original): The method of claim 8 wherein the subject is a male and the cancer is prostate cancer.

13. (Amended): A method of treating alcoholism in a subject which ~~comprises comprising~~ administering to a subject ~~in need of such treatment~~ a therapeutically effective amount of ~~the~~ a soya extract of claim 1 comprising:

(a) glucoside isoflavones of at least 13 % by weight; and

(b) 0.6 to 1.5 parts by weight of group B soya saponins per 1 part by weight of the glucoside isoflavones.

14. (Amended): ~~A method of treating alcoholism in a subject which comprises administering to a subject in need of such treatment a therapeutically effective amount of the soya extract of claim 2~~ The method of claim 13, wherein the soya extract comprises 1 part by weight of group B soya saponins per 1 part by weight of the glucoside

isoflavones.

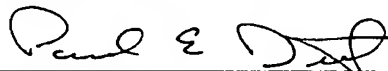
### REMARKS

Claims 5-14 are pending in this application for the Examiner's review and consideration. Claims 5-8 and 13-14 have been amended to be written in independent form. All of the amended claims are supported by the specification and claims as originally filed (*See e.g.*, Specification, page 8, lines 1-5). The title has been amended to more accurately reflect the subject matter claimed. No new matter has been added.

No fee is believed to be due for the amendments herein. Should any fee be required, please charge such fee to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

Date: June 30, 2003



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